

Environmental Protection Agency

§ 163.4

invalid, and may specify the reason for the invalidity.

(b) *Establishment registration requirements.* No person may produce any pesticide, including any pesticide registered by a State under section 24(c), unless the establishment in which it is produced is registered by the Administrator in accordance with sec. 7 of FIFRA and 40 CFR part 167.

(c) *Books and records requirements.* All producers of pesticides, including those producers of pesticides registered by States under sec. 24(c), must maintain records in accordance with the requirements imposed under sec. 8 of FIFRA and 40 CFR part 169.

Subpart E [Reserved]

PART 163—CERTIFICATION OF USEFULNESS OF PESTICIDE CHEMICALS

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AUTHORITY: 21 U.S.C. 346a.

SOURCE: 36 FR 22533, Nov. 25, 1971, unless otherwise noted.

§ 163.1 Words in the singular form.

Words in this part in the singular form shall be deemed to import the plural, and vice versa, as the case may demand.

§ 163.2 Definitions.

Unless the context otherwise requires, the following terms shall be construed, respectively, to mean:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301

et seq.), as amended by Pub. L. 518, 83d Congress, 2d Session, "An Act to amend the Federal Food, Drug, and Cosmetic Act with respect to residues of pesticide chemicals in or on raw agricultural commodities" (68 Stat. 511).

(b) *Director* means the Director of the Pesticides Regulation Division, Environmental Protection Agency, Washington, D.C.

(c) *Agency* means the Environmental Protection Agency.

(d) *Pesticide chemical* and *raw agricultural commodity* shall have the same meanings as they have in paragraphs (q) and (r), respectively, of section 201 of the Act.

(e) *Economic poison* shall have the same meaning as it has under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135-135k) and the regulations issued thereunder.

(f) *Person* means individuals, partnerships, corporations, and associations.

(g) *Certification* means a certification by the Director that a pesticide chemical is useful for the purpose for which a tolerance or exemption is sought under the act.

(h) *Petition* means a petition filed with the Administrator, Environmental Protection Agency pursuant to section 408(d)(1) of the Act.

[36 FR 22533, Nov. 25, 1971, as amended at 53 FR 15999, May 4, 1988]

§ 163.3 Administration.

The Director is authorized to take such action as, in his discretion, may be necessary to carry out the provisions of sections 408(i) and 408(l) of the Act and the regulations in this part.

§ 163.4 Filing of requests for certification.

All requests for a certification shall be made in writing to the Director. Action upon such a request will not be undertaken unless (a) the person making the request has, pursuant to the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, registered or submitted an application for the registration of an economic poison consisting of or containing the pesticide chemical for which the certification is sought and (b) the request is accompanied by a copy of the petition. The person requesting certification

may at any time withdraw such request for certification.

§ 163.5 Material in support of the request for certification.

In addition to the data required by section 408(d)(1) of the Act to be included in the petition, the request for certification should be supported by the following material, to the extent it is relied upon by the petitioner:

(a) A complete report of the results of any experimental work by the petitioner on the effectiveness of the pesticide chemical for the purposes intended;

(b) Data relating to the usefulness of the pesticide chemical obtained by other qualified investigators;

(c) Any other material which the petitioner believes will justify a finding of usefulness.

If such material is fully shown in the petition, it need not be set forth separately in the request for certification.

§ 163.6 Certification limited to economic poison uses.

If the product for which a certification is sought is intended for both economic poison and noneconomic poison uses, any certification relative to the usefulness of such product will refer only to economic poison uses. No action will be taken with respect to the noneconomic poison uses of such product.

§ 163.7 Factors considered in determining usefulness.

In determining whether a pesticide chemical is useful for the purposes for which a tolerance or exemption is sought, consideration will be given, among other things, to:

(a) The results of any experimental work by the petitioner on the effectiveness of the pesticide chemical for the purposes intended.

(b) Data relating to the usefulness of the pesticide chemical obtained by other qualified investigators.

(c) Reports of other experimental work before the Director in publications, the official files of the Agency, or otherwise.

(d) Opinions of experts qualified in the fields involved.

§ 163.8 Basis for determination of usefulness.

Usefulness of a pesticide chemical for the purposes intended will be determined upon the basis of its practical pesticidal, or biological, effectiveness. Pesticidal effectiveness may be established in terms of percentage reduction or control of pests or, when appropriate, increase in yield or quality of crop following application of the specified pesticide under the conditions prescribed, compared with the results from adequate controls. Consideration may also be given to other economic gain or practical benefit, including: Economy or ease of production, harvest, or storage of crop; flexibility as regards the time of planting or harvest, even at the possible sacrifice of yield; and general benefit to livestock, plants, or human welfare.

§ 163.9 Proposed certification; notice; request for hearing.

(a) If, upon the basis of the data before him, it appears to the Director that the pesticide chemical is not useful for the purpose or purposes for which a tolerance or exemption is sought, or is useful for only some of the purposes for which a tolerance or exemption is sought, the Director shall notify the person requesting the certification of his proposal to so certify. Notice of such proposed certification will be given by registered mail.

(b) Within one week after receipt of such notice of proposed certification the person requesting the certification may, by filing a request with the Director, (1) request that the certification be made on the basis of the proposed certification; (2) request a hearing on the proposed certification or the parts objected to; (3) request both such certification and such hearing; or (4) withdraw the request for certification as provided for in § 163.10.

If no such request or withdrawal is filed with the Director within such time, the certification will be made as proposed.

§ 163.10 Withdrawal of request for certification pending clarification or completion.

In some cases it may be necessary for the Director to notify the petitioner of